

RIXADONE®

Risperidone Oral solution 1mg/mL

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you start taking RIXADONE.

This leaflet answers some common questions about RIXADONE. It does not contain all the available information. The most up-to-date Consumer Medicine Information can be downloaded from www.ebs.tga.gov.au.

Reading this leaflet does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking RIXADONE against the benefits this medicine is expected to have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What RIXADONE is used for

RIXADONE contains risperidone. Risperidone belongs to a group of medicines called antipsychotic agents which improve the symptoms of certain types of mental illness. It works by helping to correct a chemical imbalance in the brain associated with these conditions.

RIXADONE is used for:

- treatment of sudden (acute) and long-term (chronic) schizophrenia and other types of related psychoses. These are disorders

related to thought, feeling and/or action.

- short term treatment of sudden (acute) mania associated with bipolar 1 disorder. This condition is characterised by symptoms such as elevated, expansive or irritable mood, inflated self-esteem, decreased need for sleep, pressured speech, racing thoughts, distractibility or poor judgement including disruptive or aggressive behaviours.
- treatment of behavioural problems in patients with a decline in mental ability (dementia) caused by Alzheimer's disease. These problems include aggression through words or action, morbid suspiciousness, agitation or wandering.
- treatment of conduct and other disruptive behaviours such as aggression, impulsiveness and self-injury in children (over 5 years), adolescents and adults who are intellectually disabled.
- treatment of behavioural symptoms in autism in children and adolescents.

Your doctor may have prescribed this medicine for another reason.

Ask your doctor if you have any questions about why it has been prescribed for you.

RIXADONE is only available with a doctor's prescription.

RIXADONE is not addictive.

Before you take RIXADONE

RIXADONE is not suitable for everyone

When you must not take it

Do not take RIXADONE if:

- the oral solution does not look right
- you are treating any other complaints unless your doctor says it is safe to do so.

Do not take RIXADONE if you are allergic to any medicine containing risperidone or any of the ingredients listed at the end of this leaflet.

Signs of allergy include skin rash, itching, shortness of breath, and/or swollen face - see the last section of this leaflet for a list of ingredients.

Do not take it after the expiry date printed on the pack.

If you take it after the expiry date has passed, it may not work as well.

Do not take it if the packaging is torn or shows signs of tampering.

If you are not sure whether you should start taking RIXADONE, talk to your doctor or pharmacist.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any medical conditions, especially the following:

- heart or blood vessel problems, including high and low blood pressure. Low blood pressure can

result from using RIXADONE together with medications to treat high blood pressure. So, if you need to use both RIXADONE and medications to reduce blood pressure, consult your doctor. RIXADONE should be used with caution, and only after consultation with your doctor, if you have heart problems, particularly irregular heart rhythm, abnormalities in electrical activity of the heart, or if using medications that can change the heart's electrical activity.

- disease of the blood vessels of the brain including stroke
- dehydration
- kidney or liver problems
- Parkinson's disease
- dementia or Lewy body dementia
- epilepsy, seizures
- restless or difficulty sitting still
- intraoperative iris syndrome (a complication that may occur during cataract extraction)
- suicide
- low blood potassium levels (hypokalaemia)
- low blood sugar
- breast cancer
- disease of the pituitary gland
- diabetes
- Tardive dyskinesia (a reaction to some medicines with uncontrollable twitching or jerking movements of the arms and legs).
- Neuroleptic Malignant Syndrome (a serious reaction to some medicines with a sudden increase in body temperature, extremely high blood pressure and severe convulsions).
- blood clots. Tell your doctor if you or someone else in your family has a history of blood clots. Blood clots in the lungs and legs have been seen in patients

taking RIXADONE. Blood clots in the lungs can be fatal.

- low white cell count. As dangerously low numbers of certain types of white blood cells needed to fight infection in your blood has been seen very rarely with patients taking RIXADONE, your doctor may check your white blood cell counts. Tell your doctor if you know that you have had low levels of white blood cells in the past (which may or may not have been caused by other medicines).

Tell your doctor if you are pregnant or intend to become pregnant. Your doctor will advise you whether or not you should take RIXADONE.

Shaking, muscle stiffness and difficulty in feeding, all of which are reversible, may occur in new-borns, if a mother uses the medicine in the last trimester of her pregnancy.

Do not breast-feed if you are taking this medicine.

RIXADONE is excreted into breast milk. It is recommended that you do not breastfeed while taking this medicine.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking RIXADONE.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Tell any healthcare professional who is prescribing a new medicine for you that you are taking RIXADONE. RIXADONE can increase the effects of medicines which slow your reactions.

Some medicines and RIXADONE may interfere with each other. These include:

- diuretics like frusemide, (trade names LASIX, UREMIDE,

UREX, FRUSID, or FRUSEHEXAL), a drug used to treat high blood pressure, or to treat swelling of parts of the body caused by the build-up of too much fluid. There is an increased risk of side effects or death in elderly people if frusemide is also taken with RIXADONE.

- psychostimulants like methylphenidate, medicines that increase the activity of your brain
- sleeping tablets, tranquillisers, pain-killers, antihistamines
- antibiotics like rifampicin
- carbamazepine, a drug mainly used for epilepsy or trigeminal neuralgia (severe pain attacks in the face) may decrease the level of risperidone in your blood.
- anti-fungals like itraconazole and ketoconazole,
- medicines to treat Parkinson's disease or a tremor
- medicines to treat epilepsy
- medicines to treat depression, panic disorder, anxiety or obsessive-compulsive disorder. For example, fluoxetine and paroxetine may increase the level of risperidone in your blood. So tell your doctor if you start and/or stop taking fluoxetine or paroxetine.
- medicines for your heart or blood pressure
- medicines to treat pre-menstrual dysphoric disorder
- other medicines to treat mental illness or psychotic conditions
- medicines to relieve severe
- nausea and vomiting.

The above medicines may be affected by RIXADONE, or may affect how well it works or increase the effect of other medicines. You may need different amounts of RIXADONE, or take it at different times, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be

careful with or avoid while taking RIXADONE.

How to take RIXADONE

Read the label carefully and follow all directions given to you by your doctor and pharmacist.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

How much to take

Your doctor will tell you how much RIXADONE you should take.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to take. This depends on your condition and whether or not you are taking any other medicines.

If you take the wrong dose, RIXADONE may not work as well and your problem may not improve.

Important note: never take more solution than your doctor tells you to take.

The maximum daily dose of RIXADONE is 5 milligrams taken twice a day. Check with your doctor if more than this has been prescribed. The effects of high doses are not yet known.

RIXADONE cannot be recommended for use in children with schizophrenia under 15 years at the present time as there is little experience with the product in this group.

For Schizophrenia and Related Psychoses

The usual starting dose of RIXADONE is 1 mg twice a day. This will be gradually increased by your doctor to suit your needs.

From then on, the dose can be taken once a day or twice a day according

to your doctor's instructions. For long-term treatment, 4 to 6 mg per day is usually sufficient but your doctor will determine the dose most suitable for you.

For Elderly Patients with Schizophrenia or Related Psychoses

For older patients a starting dose of 0.5 mg (or 0.5 mL of solution) twice a day (in the morning and in the evening is usual). The dose may be increased by 0.5 mg twice daily to 1 to 2 mg twice a day (in the morning and in the evening).

Patients with impaired kidney and liver function.

If you have kidney or liver disease a starting dose of 0.5 mg (or 0.5 mL of solution) twice a day (in the morning and in the evening) is usual. The dose may be increased by 0.5 mg twice daily to 1 to 2 mg twice a day (in the morning and in the evening).

For acute mania

The recommended starting dose is 2mg once a day. This dose can be adjusted by dose increases of 1mg when needed every 24 hours. Most people feel better with doses between 2mg and 6mg a day. Your doctor may decide you should take another drug called a mood stabiliser as well as RIXADONE.

For Behavioural Problems in People with Dementia

The usual starting dose is 0.25 mg twice daily. This may be gradually increased by your doctor to suit your needs.

From then on the dose can be taken once a day or twice a day according to your doctor's instructions. For long-term treatment, 1 mg daily is the usual dose but your doctor will determine the dose most suitable for you.

For Disruptive Behaviour Disorders in Adults and Children

For people who weigh 50 kg or more, the usual starting dose is 0.5 mg (or 0.5 mL of solution) once a day. The dose may be increased by 0.5 mg

once every two days, to the usual dose of 0.5 to 1.5 mg once a day.

For people who weigh less than 50 kg, the usual starting dose is 0.25 mg once a day. The dose may be increased by 0.25 mg once every two days, to the usual dose of 0.25 to 0.75 mg once a day.

Your doctor will advise you on how much RIXADONE you need.

RIXADONE cannot be recommended for use in children with disruptive behaviour disorders under 5 years at the present time as there is little experience with the product in this group.

For Behavioural Disorders Associated with Autism in Children and Adolescents

For people weighing less than 20kg the usual starting dose is 0.25mg. On day 4 this dose can be increased to 0.5mg.

For people weighing 20kg or more the usual starting dose is 0.5mg. On day 4 this dose can be increased to 1.0mg.

Response should be assessed at day 14; only in patients not achieving sufficient clinical response should additional dose increases be considered. Your doctor will advise you on how much RIXADONE you need. When trialled, the maximum dose in patients with autism did not exceed 1.5mg/day in patients less than 20kg, 2.5mg in patients 20kg or more, or 3.5mg in patients more than 45kg.

When to take it

RIXADONE may be taken as a single dose, once a day or it may be taken in divided doses twice a day (in the morning and in the evening). You may take RIXADONE either with or between meals.

How to use

Directions for opening the bottle and using the pipette for RIXADONE Oral Solution

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

The solution comes with a syringe (pipette). Use only the syringe (pipette) delivered with this medicine for measuring the dose prescribed by your doctor.

Figure 1:

The bottle comes with a child-resistant cap, and should be opened as follows

- To open, push the screw cap down while turning it anti-clockwise.
- Remove the unscrew cap

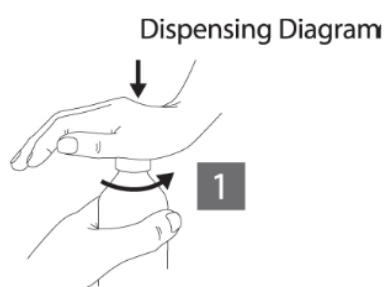


Figure 2:

Insert the pipette into the bottle.

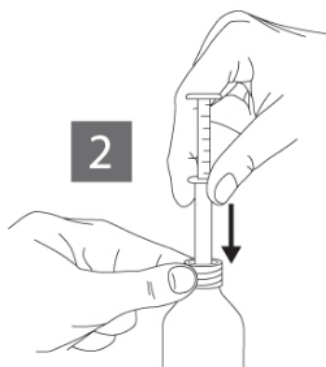
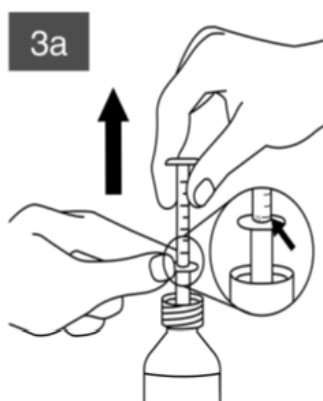


Figure 3:

While holding the bottom ring (figure 3a), pull the top ring up to the mark that corresponds to the number of milligram or millilitre you need to give (see examples Figure 3b).



Measure the exact dose of medicine you need. Pay attention when measuring a small dose, for example for 0.25 mg, measure 0.25 mL (a quarter millilitre); for 0.5 mg, measure 0.5 mL (half a millilitre).

1 mL of RIXADONE oral solution contains 1 mg risperidone. The measured volume is printed every 0.25 mL / 0.25 mg on the plunger.

Figure 3b shows examples of prescribed doses and corresponding marks on the plunger.

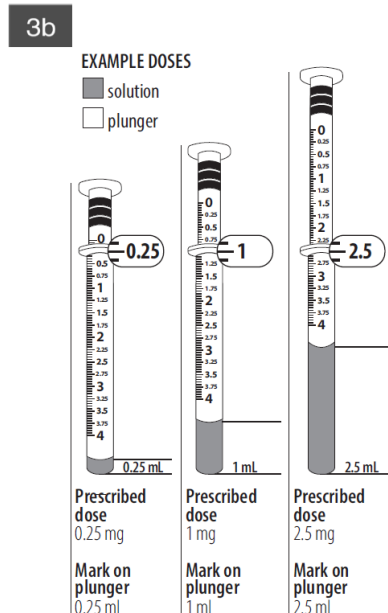


Figure 4:

Holding the bottom ring, remove the entire pipette from the bottle.

Empty the contents of the pipette into a non-alcoholic drink by sliding the upper ring down. Mineral water,

orange juice, coffee and milk are suitable. Do not use tea.

Close the bottle. Rinse the pipette with some cold water after use, let it air dry and store it in its case. Use of detergents or extensive rubbing with a cloth may increase the risk of fading or disappearing print.



How long to take it

Continue taking your medicine for as long as your doctor tells you to.

RIXADONE helps to control your condition, but does not cure it. It is important to keep taking the medicine even if you feel well.

If you are unsure whether you should stop taking RIXADONE, talk to your doctor or pharmacist.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take the next dose when you are meant to.

Do not try to make up for missed doses by taking more than one dose at a time.

This may increase the chance of getting an unwanted side effect.

If there is still a long time to go before your next dose, take it as soon as you remember, and then go back to taking it as you would normally.

If you forget to take RIXADONE for 5 days or more, tell your doctor before starting your medicine again.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for hints.

While you are taking RIXADONE

Things you must do

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking RIXADONE. Likewise, tell any other doctors, dentists and pharmacists who are treating you that you are taking this medicine.

If you become pregnant while taking this medicine, tell your doctor immediately.

Try to eat a moderate diet.

RIXADONE can cause weight gain.

Pre-menopausal women should tell their doctor if they do not have a period for more than six months while taking RIXADONE

Tell your doctor immediately if you notice any worm-like movements of the tongue, or other uncontrolled movements of the tongue, mouth, cheeks or jaw which may progress to the arms and legs.

These are symptoms of a condition called tardive dyskinesia, which may develop in people taking antipsychotic medicines, including RIXADONE. This condition is more likely to occur during long term treatment with RIXADONE, especially in elderly women. In very rare cases, this may be permanent. However, if detected early, these symptoms are usually reversible.

Try to drink plenty of water, especially if you are elderly and taking frusemide (a diuretic).

This will help decrease your risk of certain side effects.

Keep all of your doctor's appointments so that your progress can be checked.

See your doctor if you feel that your condition is not improving or is getting worse.

Things you must not do

Do not drink alcohol.

RIXADONE can increase the effects of alcohol.

Do not give your medicine to anyone else, even if they have the same condition as you.

This medicine is only intended for the person it has been prescribed for.

Do not take RIXADONE to treat any other complaints unless your doctor tells you to.

Do not stop taking RIXADONE or change the dosage without checking with your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how RIXADONE affects you.

It may cause dizziness or light-headedness in some people, especially after the first dose. Make sure you know how you react to it before you drive a car, operate machinery, or do anything else that could be dangerous if you feel dizzy. If you drink alcohol, or take strong pain killers or barbiturates, the effects may be worse.

If you feel light-headed, dizzy or faint, get up slowly when getting out of bed or standing up.

You may feel light-headed when you begin to take this medicine. This is because your blood pressure is falling suddenly. Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure.

Avoid excessive eating, as there is a possibility of weight gain when taking RIXADONE.

If you continue to feel unwell, tell your doctor.

In case of overdose

If you take too much

If you take too much

Immediately telephone your doctor, or the Poisons Information Centre (Australia – telephone 13 11 26), or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much RIXADONE.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include drowsiness, sleepiness, excessive trembling, excessive muscle stiffness, increased heart rate, very low blood pressure causing fainting or unconsciousness.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking RIXADONE.

Like all medicines, RIXADONE may occasionally cause side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Taking it for the first time.

At the start of treatment, you may have a fall in blood pressure making you feel dizzy on standing up, or your heart may beat faster. These should go away after a few days. Tell your doctor if they continue or worry you.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- difficulty thinking or working because of:

- sleeplessness or disturbances in sleep
- headache
- trembling
- drowsiness, tiredness, difficulty in concentrating
- **behavioural changes such as:**
 - agitation
 - anxiety
 - excitement or mania
- **joint or movement changes such as:**
 - muscle stiffness
 - restlessness in the legs
- **other changes such as:**
 - weight gain
 - indigestion, nausea, abdominal pain, constipation
 - excessive thirst
 - frequent urination
 - blockage in the bowel
 - unusual secretion of breast milk
 - breast swelling
 - missed or irregular menstrual periods
 - involuntary movements of the tongue, face, mouth, jaws, arms, legs or trunk
 - any eye related problem

These side effects are usually mild but may require medical attention.

Tell your doctor immediately if you notice any of the following:

- **heart or blood pressure problems such as:**
 - fall in blood pressure, particularly on standing. This will be apparent to you as lightheadedness or dizziness that passes after a few seconds or after sitting down again
 - faster heart rate, slowed heart rate, heart beat irregularities
- **body temperature changes such as:**
 - fever

- abnormally high body temperature

These may be serious side effects. You may need urgent medical attention.

Serious side effects are uncommon.

Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- serious allergic reaction (swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing)
- sudden weakness or numbness of the face, arms, or legs, especially on one side, or instances of slurred speech (these are called mini-strokes)
- in elderly patients with dementia, occurrence of following even for a short period time: sudden weakness or numbness of the face, arms or legs, especially on one side, instances of slurred speech and stroke.

These are very serious side effects; you may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some patients.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After taking RIXADONE

Storage

Keep your oral solution in the pack until it is time to take them.

If you take the oral solution out of the pack they may not keep well.

Keep RIXADONE in a cool dry place where the temperature stays below 30°C.

After RIXADONE is opened, discard it after 4 months.

Do not store it or any other medicine in the bathroom, near a sink, or on a window sill. Do not leave it in the car.

Heat and damp can destroy some medicines.

Keep it and any other medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Do not keep RIXADONE past its expiry date.

Do not use RIXADONE if the appearance of the oral solution has changed.

Disposal

Return any unused medicine and any medicine past its expiry date (as shown on the labelling) to your pharmacy.

Product description

What it looks like

RIXADONE is a clear, colourless oral solution. It is available in a 100 mL bottle with a pipette.

Ingredients

RIXADONE contains risperidone as the active ingredient.

The solution also contains the following inactive ingredients:

- tartaric acid
- benzoic acid
- hydrochloric acid
- purified water

Sponsor

Boucher & Muir Pty Ltd
Level 9, 76 Berry Street
North Sydney NSW 2060

Distributor

RIXADONE Oral Solution is
distributed in Australia by:

**Alphapharm Pty Ltd trading as
Viatis**

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatis.com.au

Phone: 1800 274 276

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